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| APPLICATION NO. | I | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------|------|-------------|----------------------|---------------------|------------------|
| 10/656,345 | | 09/05/2003 | Pamela L. Plouhar | 265280-73406 | 7805 |
| 23643 | 7590 | 01/26/2006 | | EXAM | INER |
| BARNES & | | - · | STEWART, ALVIN J | | |
| | | ' | | ART UNIT | PAPER NUMBER |
| · | | | 3738 | | |
| INDIANAPOLIS, IN 46204 | | | | | PAPER NUMBER |

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Gr. |
|--|--|---|
| | Application No. | Applicant(s) |
| | 10/656,345 | PLOUHAR ET AL. |
| Office Action Summary | Examiner | Art Unit |
| | Alvin J. Stewart | 3738 |
| The MAILING DATE of this communication app Period for Reply | pears on the cover sheet with the c | correspondence address |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING D. - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period or - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDONE | nely filed the mailing date of this communication. D (35 U.S.C. § 133). |
| Status | | |
| 1) Responsive to communication(s) filed on <u>04 N</u> | lovember 2005. | |
| 2a)⊠ This action is FINAL . 2b)☐ This | s action is non-final. | |
| 3) Since this application is in condition for allowa | nce except for formal matters, pro | osecution as to the merits is |
| closed in accordance with the practice under E | Ex parte Quayle, 1935 C.D. 11, 49 | 53 O.G. 213. |
| Disposition of Claims | | |
| 4) Claim(s) 1-5,7-11,14,15,17 and 18 is/are pend | ling in the application. | |
| 4a) Of the above claim(s) is/are withdra | wn from consideration. | |
| 5)⊠ Claim(s) <u>10,15 and 17</u> is/are allowed. | | • |
| 6)⊠ Claim(s) <u>1,14 and 18</u> is/are rejected. | | |
| 7) Claim(s) <u>2-5, 7-9</u> is/are objected to. | | |
| 8) Claim(s) are subject to restriction and/o | or election requirement. | |
| Application Papers | | |
| 9)☐ The specification is objected to by the Examine | er. | |
| 10) The drawing(s) filed on is/are: a) acc | epted or b) objected to by the | Examiner. |
| Applicant may not request that any objection to the | *** | |
| Replacement drawing sheet(s) including the correc | | |
| 11) ☐ The oath or declaration is objected to by the Ex | xaminer. Note the attached Office | Action or form PTO-152. |
| Priority under 35 U.S.C. § 119 | | |
| 12) Acknowledgment is made of a claim for foreigna) All b) Some * c) None of: | priority under 35 U.S.C. § 119(a |)-(d) or (f). |
| Certified copies of the priority document | ts have been received. | |
| Certified copies of the priority document | ts have been received in Applicat | ion No |
| Copies of the certified copies of the prior | rity documents have been receive | ed in this National Stage |
| application from the International Burea | | |
| * See the attached detailed Office action for a list | of the certified copies not receive | ed. |
| | | |
| | | |
| Attachment(s) | | |

U.S. Patent and Trademark Office PTOL-326 (Rev. 7-05)

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date _

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)

4) Interview Summary (PTO-413)

6) Other: __

Paper No(s)/Mail Date. ____

5) Notice of Informal Patent Application (PTO-152)

Response to Arguments

Applicant's arguments with respect to claims 1, 14 and 18 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vacanti et al US Patent 6,027,744.

Vacanti et al discloses a prosthetic device comprising an extracellular matrix portion (14) having a solidify hydrogen composition (16) with live cells (18) and a synthetic mesh portion (12) coupled to the extracellular portion (see col. 11, lines 1-20). The synthetic material and the extracellular matrix portion are biodegradable (see col. 5, lines 21-24; and col. 7, lines 10-11). Additionally, the synthetic fiber is made of Vycryl (see col. 6, lines 1-4). Regarding the extracellular matrix, the claims disclosed above are given their broadest reasonable interpretation. In re Pearson, 181 USPQ 641 (CCPA 1974). For the above reasons, the Examiner has used only a prosthetic device having tissue precursor cells.

Regarding the new limitations in claim 1, it is an inherent characteristic of biocompatible polymeric struts (12) to have a rate of absorption slower than the extracellular matrix. It has been held that a claim is anticipated if each element of the claim is found, either expressly

described or under principles of inherency, in a single prior art reference, or that the claimed invention was previously known or embodied in a single prior art device or practice. Kalman vs. Kimberly-Clark Corp., 218 USPQ 789. However, Vacanti et al does not disclose a sheet of bioabsorbable synthetic mesh having a rate of absorption that is slower than a rate of absorption of the naturally occurring matrix.

It would have been obvious to one having ordinary skill in the art to have a biocompatible support structure having an absorption rate slower than the absorption rate of a drug or a natural occurring matrix so the support structure can maintain the structure shape until the drug or natural occurring matrix is delivered (as shown in the Vacanti et al reference).

It has been held that a claim is anticipated if each element of the claim is found, either expressly described or under principles of inherency, in a single prior art reference, or that the claimed invention was previously known or embodied in a single prior art device or practice. Kalman vs. Kimberly-Clark Corp., 218 USPQ 789.

Allowable Subject Matter

Claims 2-5, 7-9, 11, and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 10, 15 and 17 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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final action.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. U. 3738

ALVIN J. STEWART

A. Stens

April 01, 2005.